

REMARKS

Claims 1, 19, 21, 24, 30-32 and 35-63 are pending in this application. Claims 1, 19, 21, 24, 30-32 and 35-36 stand rejected, and claims 37-63 are withdrawn. Reconsideration is respectfully requested.

Prima Facie Case For Obviousness Has Not Been Made in First Rejection

The first rejection rejects claims 1, 19, 21, and 24 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,482,386 to *Wittwer et al.* in view of U.S. Patent No. 4,124,705 to *Rothman et al.*, and U.S. Patent No. 4,515,637 to *Cioca*.

According to MPEP § 2143, to support a *prima facie* case of obviousness, it is important to identify a reason that would have prompted the artisan to combine the elements in the way the presently claimed new invention does. Moreover, all claim elements must be considered and shown to be present when determining patentability against the cited references. Applicants submit this burden has not been met.

Independent Claim 1

Equilibrium Swell

Independent claim 1 recites that the colloid has an equilibrium swell from between 400% to 5000%. At page 9, line 11, the Office Action correctly quotes the Applicants' argument that, "*Wittwer* does not mention equilibrium swell value ranges at all." Hence, it is believed that the Office Action statement at line 17 that "applicants rightly pointed out that *Wittwer* does suggest obtaining equilibrium swell." is an inadvertent error.

At page 9, lines 20-22, the Office asserts that "the burden is on applicants to show that the finite and incomplete list of crosslinkers of *Wittwer* do not provide an equilibrium swell anywhere between 400% to 5000%." The Office, however, fails to provide a citation to the MPEP, the CFR, or any other authority that places such a burden on the Applicant, and Applicants are unaware of such a burden. The Applicants respectfully submit that MPEP § 2143 clearly places the burden on the Office of finding that the cited references disclose each element claimed. Thus, the Applicants request a citation to any authority which places the burden on

Applicants to prove that an element which is not expressly disclosed by a cited reference is also not implicitly disclosed.

Similarly, the Office has stated at page 10, line 19, that “*Wittwer* is directed to solving the same problem as that of the instant invention, i.e., obtain equilibrium swell,” but the Applicants are unable to find in *Wittwer* such a goal. *Wittwer* does state that the process is to reach equilibrium with a “predetermined water content,” however this is not the same as equilibrium swell of a colloid, as would be understood by one of skill in the art. For a colloid to reach equilibrium with a predetermined water content it only need absorb that amount of water, and this is not comparable to an equilibrium swell value of the colloid itself. Hence, not only does *Wittwer* fail to describe equilibrium swell conditions, *Wittwer* has not been shown to teach reaching equilibrium swell, which as noted above is different from equilibrium with predetermined water content.

Alternatively, although the Office has not stated such, the Office may be relying on the presence of inherent features or Official Notice. Should the Office be relying on Official Notice, the Applicants challenge the Examiner’s use, and request a showing pursuant to MPEP § 2144.03.

If instead the Office is relying on inherency of equilibrium swell values from between 400% to 5000%, the Applicants believe that this rationale is unsupported. As stated in MPEP § 2112(IV), in order to show inherency the Office must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. That section additionally states that the fact that a certain result or characteristic may occur or be present in a technical reference is not sufficient to establish inherency. The Office has not made this clear, and thus again, the Applicants request a showing that these equilibrium swell values would be necessarily present.

Finally, if the Office is relying on an “obvious to try” rationale based on the remarks regarding finite number and optimization on pages 10-11, the Applicants request that the Office make a showing that cites specifically, as required by MPEP § 2143, that there was a recognized problem in the art, as well as a finite number of identified predictable potential

solutions to the recognized problem. Because this is not the stated rationale within the Office Action at pages 5-6, the Applicants request clarity as to how these comments are applicable to the specific rejection and rationales made.

The Office Action concludes at pages 10-11 that Wittwer suggests a finite number of possibilities leading to the presently claimed equilibrium swell. This is wrong.

Wittwer in fact provides no direction as to which of many possible choices are likely to be successful in obtaining the presently claimed equilibrium swell. For example, at col. 2 lines 49-60, Wittwer only vaguely states that the hydrophilic polymer may be modified by crosslinking agents such as salts or tri or tetravalent metals, aldehydes, dialdehydes, halogenated aldehydes, mucochloric acid, 1,1- and 1-4 diketones, quinones, acid anhydrides, vinylsulfones, acrylamides, products with 3-membered rings such as ethyleneoxide or ethyleneimine, carbamoylonium compounds, *etc.*, and that by such crosslinking agents the water-swellability can be varied within wide limits.

It strains the bounds of credulity to suggest that Wittwer *guides* the artisan toward a *particular* solution, by providing a finite number of *identified and predictable* solutions, and that the finite number of options is *small or easily traversed*, as required by the “obvious to try” rationale (see also Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1364 (Fed. Cir. 2008)).

Degradation Time

Claim 1 additionally recites that the colloids have an *in vivo* degradation time of less than one year. Wittwer does not disclose this claimed element. Page 8, line 1, of the final Office Action states that “Applicants have not shown that the hydrocolloids of *Wittwer* do not possess the said characteristic.” Again, Applicants request a showing of under what authority such a burden is placed on the applicants. Should the Office be relying on Official notice or inherency, the remarks above are equally applicable, and the same remarks are reiterated here requesting a showing of proof.

Additionally, the Office states at page 10, line 19, that again *Wittwer* is directed to solving the same problem as the instant application of “avoiding rapid degradation.” Applicants

cannot agree. Initially, *Wittwer* is specifically directed to using hydrocolloids for use in “mechanical forming processes such as die molding or injection molding,” as stated in the abstract. There is no indication that such compounds are ever used *in vivo*. This is also a mischaracterization of the stated elements. The recitation of claim 1 specifically states that the hydrocolloid degrades within a year. *Wittwer*, on the other hand, seeks to “avoid chemical and mechanical degradation” unrelated to time, as stated at col. 1, lines 62-63. This cannot be considered the same goal, and thus if the Office is basing these determinations on an “obvious to try” rationale, the Applicants believe that based on the above, the Office has not met the burden required by this rationale of showing the problem recognized in the art.

Single Phase and Substantially Free From a Free Aqueous Phase

The *Rothman* reference is cited specifically for its use of a polysaccharide, but that reference only describes a polysaccharide in aqueous suspension. The Office, after admitting that *Rothman* only discusses suspensions, provides the following rationale for combination:

However, instant rejection includes a combination of *Wittwer*, *Rothman*, and *Hubbell* for the claimed combination of protein and a polysaccharide and even though *Rothman* teaches a suspension of polysaccharide, *Wittwer* teaches any hydrocolloid polymer and *Hubbell* teaches injectable hydrogel polymers that include mixtures of polymers. Hence, a skilled artisan would have been motivated to include a mixture of protein and polysaccharide in the hydrogel particles in the same phase and not a suspension of polysaccharide that is mixed with gelatin hydrogel.

The Applicants cannot agree that a skilled artisan would be so motivated, and further submit that the Office has not provided a plausible rationale as to why the artisan would be so motivated.

Initially, this remark is improper because *Hubbell* is not utilized in the combination of references cited against claim 1. Secondly, this paragraph directly conflicts with the Office’s statements on page 5, lines 8-12, stating that it is *Rothman* that allegedly reads on

single phase and free from a free aqueous phase. Additionally, no reason has been shown why the teaching of a suspension, which is the opposite of both single phase and free from a free aqueous phase, would change in combination. Without providing any rationale for combination, the combination cannot be made if for no other reason than because the combination would not teach the recitations of claim 1, because *Rothman* teaches the opposite of specific recitations. Moreover, no rationale has been provided for modifying the teaching of *Rothman*, or why a skilled artisan would determine that such a modification is necessary, or that such a modification would function correctly.

Essentially, there is no proper combination of these references that could possibly teach or suggest the recitations of the present claim.

Cioca does not remedy these deficiencies of *Wittwer* or *Rothman*, as it is cited only for its use of thrombin, and thus for at least these reasons, claim 1 is believed nonobvious and allowable over the cited references. Accordingly, withdrawal of the rejection is respectfully requested. Hence, as no proper rationale for combining the references has been provided, the Applicants request withdrawal of the rejection, because a *prima facie* case of obviousness has not properly been shown.

Dependent Claims 19, 21, and 24

As claims 19, 21, and 24 each depend directly from claim 1, they are believed allowable at least by virtue of their dependence from an allowable claim. Accordingly, withdrawal of the rejection of these claims is respectfully requested.

Prima Facie Case for Obviousness Has Not Been Made in Second Rejection

The second rejection rejects claims 30-32 and 35-36 under 35 U.S.C. § 103(a) as being unpatentable over *Wittwer* in view of *Rothman* and *Cioca* as applied to claims 1, 19, 21 and 24 above, and further in view of U.S. Patent No. 6,129,761 to *Hubbell*.

Hubbell is cited for describing injectable compositions, and does not remedy the deficiencies of *Wittwer*, *Rothman*, and *Cioca*. Thus, as claims 30-32 depend from claim 1, they are believed allowable at least by virtue of their dependence from an allowable base claim. The

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references as applied to claim 1 are also deficient with regard to claims 35 and 36 for each of the reasons stated with regard to claim 1, and the remarks presented previously are applicable to claims 35 and 36 as well. Thus withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at .

Respectfully submitted,

/Daniel K. McCormick/

Daniel K. McCormick
Reg. No. 67,699

KILPATRICK TOWNSEND & STOCKTON LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 303-571-4000
Fax: 415-576-0300
D5M:seo
63728510 v1